

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

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## PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing  
(day/month/year) **17-04-2007**

Applicant's or agent's file reference

**P4199PC00**

**FOR FURTHER ACTION**

See paragraph 2 below

International application No.

**PCT/SE2006/001129**

International filing date (day/month/year)

**05-10-2006**

Priority date (day/month/year)

**07-10-2005**

International Patent Classification (IPC) or both national classification and IPC

See Supplemental Box

Applicant

**PROSTALUND OPERATIONS AB et al**

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further opinions, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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International application No.

PCT/SE2006/001129

**Supplemental Box**

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Cover sheet

**International patent classification (IPC)**

**A61M 25/10 (2006.01)**

Box No. 1 Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed  
☐ a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a)).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing  
☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper  
☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.  
☐ filed together with the international application in electronic form.  
☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The question whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

- ☐ the entire international application
- ☒ claims Nos. 19-44

because:

- ☒ the said international application, or the said claims Nos. 19-44

relate to the following subject matter which does not require an international search (*specify*):

See PCT Rule 67.1.(iv): Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_ are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

- ☐ no international search report has been established for said claims Nos. \_\_\_\_\_
- ☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:
- ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
  - ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
  - ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13ter.1(a) or (b).
- ☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in the Annex C-bis of the Administrative Instructions.
- ☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/SE2006/001129

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>1-18</u>	YES
	Claims		NO
Inventive step (IS)	Claims	<u>2-5, 8-16, 18</u>	YES
	Claims	<u>1, 6-7, 17</u>	NO
Industrial applicability (IA)	Claims	<u>1-18</u>	YES
	Claims		NO

2. Citations and explanations:

Reference is made to the following document:

D1: WO 02092158 A2

The invention relates to a partial-length indwelling catheter for draining urine from a male human. The catheter comprises a main body defining an interior passageway communicating with the urine within the bladder. The catheter further includes a distal anchor element that is expandable in size to contact the bladder neck and restrain the main body against proximal movement. A control element is connected to the main body and extends outside the exterior opening, being capable of transferring force from the proximal end of the control element to the main body to selectively displace the proximal end of the catheter in a proximal direction, from the normal position through the orifice of the external urinary sphincter muscle. The invention solves the problem of having a catheter that allows the user to selectively open a passageway for the drainage of urine through an obstructed urethra or a constricted external urinary sphincter muscle having the advantage of being positioned completely inside the prostatic urethra.

Document D1 is considered to represent the closest prior art. D1 describes a partial-length catheter for draining urine from a male human. The catheter comprises a main body,

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Supplemental Box

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with a prostatic (10) and a bulbar (20) segment, defining an interior passageway communicating with the urine within the bladder. The segments being connected by ties (5, 14) to allow the catheter to assume at least to different inter-segmental distances. The catheter further includes a distal anchor element (1) that is expandable in size to contact the bladder neck and restrain the main body against proximal movement. A control element (16) is connected to the ties between the two segments of the main body and extends outside the exterior opening, being capable of transferring force from the proximal end of the control element (16) to the main body to selectively displace the bulbar segment (20) of the catheter from the normal position through the orifice of the external urinary sphincter muscle. See page 7 rows 8-16 and 24-30, page 8 rows 1-6 and the entire page 10 as well as figures 2A and 2B.

The invention according to claim 1 differs from the device in D1 in that the catheter is entirely positioned inside the prostatic urethra. By pulling the control cord the proximal end of the main body is moved in the proximal direction through the orifice of the external urinary sphincter muscle. In D1 the proximal end of the main body needs to be moved in a distal direction to be positioned in the orifice of the external urinary sphincter muscle.

Due to these features, a more compact catheter is obtained. Consequently, with the background of D1, the problem is to design a device which can be entirely positioned within the prostatic urethra.

A person skilled in the art, wanting to solve the problem as described above would simply shorten the entire length of the main body to fit within the prostatic urethra. By pulling the control cord the proximal part would move in the proximal direction through the orifice of the external urinary sphincter muscle, thereby arriving at the invention. Thus, the subject-matter of claim 1 does not involve an inventive step and does not satisfy the criterion set forth in Article 33(3) PCT.

Claim 6 declares that the catheter should have a mechanical

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Supplemental Box

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Continuation of: BOX V

integrity preventing it from collapsing when the force on the control element is sufficient to pull the main body into the orifice of the external urinary sphincter muscle. This may be considered to be known by the skilled person wanting to produce a lasting indwelling catheter.

The features of dependent claims 7 and 17 have already been employed for the same purpose in document D1. It would therefore be obvious to the person skilled in the art to apply these features with corresponding effect to a catheter according to the invention.

Therefore, the invention according to claims 6, 7 and 17 is not considered to involve an inventive step.

All claims are novel and industrially applicable.